

1 Jeffrey M. Singletary, Bar No. 233528  
jsingletary@swlaw.com  
2 Justin F. Mello, Bar No. 329514  
jmello@swlaw.com  
3 SNELL & WILMER L.L.P.  
600 Anton Blvd, Suite 1400  
4 Costa Mesa, California 92626-7689  
Telephone: 714.427.7000  
5 Facsimile: 714.427.7799

6 Attorneys for Non-Party  
7 ALLIANCE HEALTHCARE PARTNERS LLC

8  
9  
**UNITED STATES DISTRICT COURT**  
**FOR THE NORTHERN DISTRICT OF CALIFORNIA**  
10  
**SAN FRANCISCO DIVISION**

11 SURGICAL INSTRUMENT SERVICE  
COMPANY, INC.,

Lead Case No. 3:21-CV-03496-VC  
Hon. Vince Chhabria  
Dept. 5

12 Plaintiff/  
13 Counterclaim-Defendant

**DECLARATION OF JEFFREY L.**  
**BERHOLD IN RESPONSE TO**  
**DEFENDANT INTUITIVE**  
**SURGICAL, INC.'S MOTION TO**  
**CONSIDER WHETHER**  
**ANOTHER PARTY'S**  
**MATERIAL SHOULD BE**  
**SEALED PURSUANT TO CIVIL**  
**LOCAL RULE 79-5(f)**

14 vs.

15 INTUITIVE SURGICAL, INC.,

16 Defendant/  
17 Counterclaim-Plaintiff.

SNELL & WILMER  
L.L.P.  
600 ANTON BLVD, SUITE 1400  
COSTA MESA, CALIFORNIA 92626-7689

18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

1 I, Jeffrey L. Berhold, declare as follows:

2       1. I am over the age of eighteen years old and am counsel for non-party  
 3 Alliance Healthcare Partners LLC (“Alliance”). Unless otherwise indicated, I state  
 4 the following of my own personal knowledge and, if called upon to do so, I could  
 5 and would testify competently to the following.

6       2. Pursuant to Civil Local Rules 7-11 and 79-5(f), Alliance submits this  
 7 declaration in response to defendant Intuitive Surgical, Inc.’s (“Intuitive”)  
 8 Administrative Motion to Consider Whether Another Party’s Material Should Be  
 9 Sealed. Alliance seeks to maintain the confidentiality of AHP000527 from its  
 10 510(k) application for repairing EndoWrists and requests that the Court seal the  
 11 document itself and redact quotations from it and references to it.

12       3. Alliance filed a 510(k) application with the FDA (K210478) on behalf  
 13 of non-party Restore Robotics Repairs LLC (“Restore”). The 510(k) application  
 14 concerns the development, testing, and regulation of proposed methods for  
 15 repairing EndoWrists. The application was submitted with the understanding based  
 16 on FDA regulations that the agency would only disclose the 510(k) summary – and  
 17 only disclose the public summary after clearance. *See* 21 C.F.R. § 20.61(c). The  
 18 courts of this district and circuit have routinely sealed 510(k) applications because  
 19 the information in such documents is valuable and its disclosure to competitors  
 20 would be extremely damaging. *See, e.g., Edwards Lifesciences Corp. v. Meril Life*  
*Scis. PVT. Ltd.*, No. 19-CV-06593-HSG, 2020 WL 6118533, at \*11 (N.D. Cal. Oct.  
 21 16, 2020), *Lucas v. Breg, Inc.*, No. 15-cv-00258-BASNLS, 2016 WL 5464549, at  
 22 \*2 (S.D. Cal. Sept. 28, 2016) (sealing 510(k) premarket submission to the FDA  
 23 addressing safety and effectiveness of device).

24       4. Alliance produced the 510(k) application, including correspondence  
 25 with the FDA, for Attorney’s Eyes Only under a subpoena and protective order in  
 26 *Restore Robotics, LLC v. Intuitive Surgical, Inc.* (N.D. Fla. 19-cv-55). Alliance  
 27 later consented to its production by Intuitive in this matter under a similar

1 protective order. Since production in this matter, the FDA has cleared K210478  
 2 and published the 510(k) summary. After clearance, Alliance conveyed the 510(k)  
 3 clearance to Restore through the sale of the 510(k) applicant Iconocare Health  
 4 Solutions. Earlier this year, Restore resolved its dispute with Intuitive.

5       5. Consistent with industry practice, Alliance and Restore have always  
 6 maintained the 510(k) file within a closely held group of individuals on a need-to-  
 7 know basis within the companies. Disclosure would give substantial assistance to  
 8 potential competitors – allowing them to avoid potentially years of time and  
 9 millions of dollars required to develop their own production and testing methods  
 10 and regulatory strategy.

11       6. Intuitive has provided notice that it has provisionally filed an eleven-  
 12 page letter from the FDA to Alliance regarding K210478 (AHP000527) under seal  
 13 with several motions to exclude testimony of expert witnesses. I represented  
 14 Alliance and Restore in *Restore Robotics v. Intuitive Surgical* and represent  
 15 Alliance and Restore regarding the confidentiality of AHP000527. Neither  
 16 Alliance nor Restore has disclosed AHP000527 to any third party because it would  
 17 allow competitors to make use of Alliance and Restore's extensive efforts to  
 18 commercialize repaired EndoWrists. The letter is part of a dialogue between the  
 19 applicant and the agency regarding the development, testing, and regulation of  
 20 proposed methods for repairing EndoWrists. Disclosure would provide competitors  
 21 with a significant head start in their own efforts.

22       7. Moreover, it would bring significant risk of confusion to the public  
 23 because the correspondence is far from the final word on the production, testing,  
 24 and marketing eventually cleared in the application on September 30, 2022. *See,*  
 25 *e.g., Sarafin v. BioMimetic Therapeutics, Inc.*, No. 3:11-0653, 2013 WL 139521, at  
 26 \*18 (M.D. Tenn. Jan. 10, 2013) (“What is clear, however, is that a deficiency letter  
 27 is not a final FDA decision, but a request for more information, and, in fact, ‘very  
 28 few’ PMA are approved without the issuance of a deficiency letter.”). In fact, the

1 FDA has cleared the application and published the 510(k) summary, which governs  
2 the clearance.

3  
4 I declare under penalty of perjury under the laws of the United States of  
5 America that the foregoing is true and correct.

6  
7 Executed: March 29, 2023

  
\_\_\_\_\_  
Jeffrey L. Berhold

SNELL & WILMER  
L.L.P.  
LAW OFFICES  
600 ANTON BLVD, SUITE 1400  
COSTA MESA, CALIFORNIA 92626-7689

10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28